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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,783	12/08/2003	L. Dean Parks	1238.009	4821
27353 7590 04/20/2007 MELVIN K. SILVERMAN 500 WEST CYPRESS CREEK ROAD SUITE 500 FT. LAUDERDALE, FL 33309			EXAMINER KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER
			1618	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/20/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/730,783	Applicant(s) L. DEAN PARKS	
	Examiner Vickie Kim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9 and 10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Status of Application

1. The claims 1-5, 7 and 9-10 are pending and presented for the examination.

Response to Arguments

1. Applicant's arguments with respect to pending claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 7 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Komer (US 5773422) in view of Miller(US5728719).

The claims are drawn to a topical composition consisting essentially of an avermectin compound and a pharmaceutically acceptable carrier, where amount of avermectin compound is present in a concentration range from about 0.05 to 0.075%(w/v).

Komer(US'422, hereinafter) teaches topical avermectin formulation containing 0.1 to 40%(w/v) avermectin such as ivermectin, see col. 3, lines 6-7 and col. 2, line 15 and col.4, lines 19-20. As to claims 1-3 and 5, US'422 teaches topical pour-on

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composition containing 5mg/ml(converted to 0.5% w/v) ivermectin, propylene glycol or water as carrier.

As to claims 7 and 9-10, US'422 teaches a dermatological composition comprising an avermectin integrated in one form of dermal patch, see col.4, lines 19-20.

Although Komer(US'422) does not teach 0.05-0.075%, the claimed invention is not patentably distinct over prior art of the record when US'422 is taken in view of McDaniel(US'372) and Miller (US'719, hereafter) because, firstly, McDaniel teaches 1-5% ivermectin containing topical composition, see col. 3, lines 8-9. McDaniel further teaches that enhanced penetration of said topical composition can be achieved by a formulation utilizing microliposomes which indirectly teaches lowered amount of active agent is required for equivalent result.

Secondly, Miller(US'719, hereinafter) teaches a topical application containing avermectin compound such as ivermectin, see abstract; col. 9, lines 17; and col. 10, lines 30-32, 40 and 51. For example, topical gel (example 10, at col 14) contains primary active agent present in about 5.8%w/v based on (12g/206g water(about 206ml). US'719 also teaches avermectin compound(second agent) present in about 0.005-0.5%(10^{-1} to 10^{-3} of primary ingredient, see col. 10, lines 59-61 and col. 14, lines 56-57). Based on Miller's teaching, one would have been easily calculated the effective amount of avermectin included in combination. Thus, the skills and techniques to make a topical composition containing low concentration as low as 0.005% of avermectin compound is well supported by Miller's patent .

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One would have been motivated to make a product as effective and lowest concentrated as possible because unwanted side effect can be reduced and the industrial applicability can be maximized.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

"Consisting Essentially Of"

Applicants argues in view of amend claims where amended claims are now patentably distinguish over Komer or Miller in view of the transition phrase "consisting essentially of"(Request for reconsideration and withdrawal of the rejection, see Remark section at page 6, filed 1/31/05). However, applicant's argument is not persuasive. According to applicants, the recitation of an active component in those claims "consisting essentially of" avermectin exclude penetration enhancer (e.g. N-methylpyrrolidone from Komer US'422 patent) or (e.g. pyriproxifen disclosed by US'719, to Miller).

As stated in PPG Indus., Inc. V. Guardian Indus. Corp., 156 F 3d 1351, 1355, 48 USPQ 2d 1351, 1353-1354(Fed. Cir. 1998),

By using the term "consisting essentially of," the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A "consisting essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully open claims that are drafted in a "comprising" format.(Emphasis added).

In light of applicant's own disclosure, applicant uses Cetaphil® as a carrier. However, Cetaphil® contains glycerin, hydrogenated polyisobutene, cetearyl alcohol, and cetareth-20, macadamia nut oil, dimethicone. Tocopheryl acetate, stearoxytrimethylsilane and stearyl alcohol, panthenol, farnesol, benzyl alcohol, phenoxyethanol, acrylates.C10-30 alkyl acrylate crosspolymer, citric acid, etc., see specification at page 24. Here, applicants' argument that "consisting essentially of" which excludes those additives(e.g. penetration enhancers or other active agent) found in Komer or Miller, is an example of ipse dixit reasoning. Applicants do not describe the "basic and novel properties of the invention," or explain why all the ingredients included in Cetaphil® are not materially affecting novelty of the invention.

Additionally, it is apparent from applicant's specification(page 24) that the composition of the claimed method may include a host of ingredients or additives. These additives are penetration enhancers, additional active agent which benefitally enhancing therapeutic efficacy, and also rate controlling polymers, etc(see PTO-892 for supporting documents).

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L6 ANSWER 4 OF 11 USPAIFULL on STN

DETD . . . polymers, cationic polymers, denaturants, cosmetic astringents, drug astringents, external analgesics, film formers, plasticizers, preservatives, preservative enhancers, propellants, reducing agents, additional skin-conditioning agents, skin penetration enhancing agents, skin protectants, solvents, suspending agents, emulsifiers, nonionic surfactants, anionic surfactants, cationic surfactants, zwitterionic surfactants, amphoteric surfactants, Gemini surfactants, hydrotropes, . . . agents, solubilizing agents, sunscreens, sunblocks, ultraviolet light absorbers or scattering agents, sunless tanning agents, antioxidants, radical scavengers, chelating agents, sequestrants, anti-acne agents, anti-inflammatory agents, anti-androgens (such as pregnenolone and its derivatives, hops extract, oxygenated alkyl substituted bicyclo alkanes like ethoxyhexyl-bicyclo octanones, . . . allantoin, bisabolol, dipotassium glycyrrhizinate and the like, sunscreens, thickeners, vitamins and derivatives thereof (e.g., ascorbic acid, vitamin B.sub.3, vitamin E, tocopheryl acetate, retinoic acid, retinol, retinoids, and the like), water and viscosity adjusting agents. This list of optional components is not meant.

ACCESSION NUMBER: 2004:100793 USPAIFULL Full-text
TITLE: Branched alcohol-based personal care compositions
INVENTOR(S): Vinson, Philip Kyle; Fairfield, OH, UNITED STATES
Stidham, Robert Emerson, Lawrenceburg, IN, UNITED STATES
Connor, Daniel Stedman, Cincinnati, OH, UNITED STATES
Heffner, Jack Clinton, Cincinnati, OH, UNITED STATES
Cripe, Thomas Anthony, Loveland, OH, UNITED STATES
Scheibel, Jeffrey John, Loveland, OH, UNITED STATES
Kott, Kevin Lee, New Castle Upon Tyne, UNITED KINGDOM
PATENT ASSIGNEE(S): The Procter & Gamble Company (U.S. corporation)

	NUMBER	KIND	DATE
PATENT INFORMATION:	US 2004076654	A1	20040422
APPLICATION INFO.:	US 2003-647974	A1	20030826 (10)

	NUMBER	DATE
PRIORITY INFORMATION:	US 2002-408826P	20020907 (60)
DOCUMENT TYPE:	Utility	
FILE SEGMENT:	APPLICATION	
LEGAL REPRESENTATIVE:	THE PROCTER & GAMBLE COMPANY, INTELLECTUAL PROPERTY DIVISION, WINTON HILL TECHNICAL CENTER - BOX 161, 6110 CENTER HILL AVENUE, CINCINNATI, OH, 45224	
NUMBER OF CLAIMS:	20	
EXEMPLARY CLAIM:	1	
LINE COUNT:	891	

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L6 ANSWER 5 OF 11 USPAIFULL on STN

AB . . . the delivery of topical agents to the skin including a polymer matrix, generally a hydrogel matrix having adhesive properties, a skin conditioner and a penetration enhancer. The hydrogel matrix including purified water, glycerin, polyacrylate, sorbitol, kaolin, CMC (carboxymethyl cellulose), alcohol, castor oil, TWEEN 80 (polyoxyethylene sorbitan monooleate), fragrance and citric acid. Skin conditioners and penetration enhancers including methyl sulfonyl methane, glucosamine and chondroitin. The matrix may also include a topically effective drug. The adhesive patch includes.

ACCESSION NUMBER: 2003:257297 USPAIFULL Full-text
TITLE: Patch for the delivery of topical agents
INVENTOR(S): Young, Tyler F., Hampden, MA, UNITED STATES
Hayes, Harry, Hampden, MA, UNITED STATES
PATENT ASSIGNEE(S): W.F. YOUNG, INCORPORATED, East Longmeadow, MA, UNITED STATES (U.S. corporation)

	NUMBER	KIND	DATE
PATENT INFORMATION:	US 2003180347	A1	20030925
APPLICATION INFO.:	US 2003-388300	A1	20030313 (10)

	NUMBER	DATE
PRIORITY INFORMATION:	US 2002-365193P	20020319 (60)
DOCUMENT TYPE:	Utility	
FILE SEGMENT:	APPLICATION	

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L6 ANSWER 10 OF 11 USPATFULL on STN

DETD The compositions of this invention are administered topically to treat acne vulgaris. That is, the compositions may be applied as a solution, gel, ointment, cream, a liquid suspension or emulsion or . . . of fatty acids; conventional emollients, such as isopropyl and butyl esters of fatty acids, e.g. isopropyl myristate; humectants such as glycerin, propylene glycol, polyethylene glycol; and alcohols and acetone; oils such as mineral oil, petroleum oil, oil extracts from animal or . . . urea, to improve the hydration of the skin. In addition to the foregoing conventional formulations, the topical compositions may include penetration-enhancing agents such as 1-pyrrolidone and N-lower alkyl-2-pyrrolidones, such as N-methyl-2-pyrrolidone; and 1-substituted azacycloalkan-2-ones such as, for example, 1-n-dodecylazacycloheptan-2-one and other compounds disclosed in U.S. Pat. No. 3,989,816. Longer chain sulfoxides, e.g., n-octyl methyl sulfoxide and hexamethylene-lauramide and the other penetration-enhancing agents disclosed in U.S. Pat. No. 4,743,598, may also be included in the formulations utilized in the method of this invention. The amount of these penetration-enhancing agents which may be used in the present invention ranges from about 0.1 to 25 percent and preferably about 1. . . .

ACCESSION NUMBER: 2001:112382 USPATFULL Full-text
 TITLE: Method and composition for treating acne
 INVENTOR(S): Sefton, John, Trabuco Canyon, CA, United States
 PATENT ASSIGNEE(S): Allergan Sales, Inc., Irvine, CA, United States (U.S. corporation)

	NUMBER	KIND	DATE
PATENT INFORMATION:	US 6262117	B1	20010717
APPLICATION INFO.:	US 1999-252318		19990218 (9)
DOCUMENT TYPE:	Utility		
FILE SEGMENT:	GRANTED		
PRIMARY EXAMINER:	Jarvis, William R. A.		
ASSISTANT EXAMINER:	Kim, Vickie		
LEGAL REPRESENTATIVE:	O'Donohue, Cynthia H., Baran, Robert J., Voet, Martin A.		
NUMBER OF CLAIMS:	10		
EXEMPLARY CLAIM:	1		
LINE COUNT:	335		
CAS INDEXING IS AVAILABLE FOR THIS PATENT.			

L6 ANSWER 11 OF 11 USPATFULL on STN

SUMM . . . singly or in topical preparations, are known either to induce irritation, sensitization, or allergic skin reactions and/or to be skin penetration enhancers. Humectants (such as for examples, glycerin), solvents (such as, for example, polyethylene glycol), sunscreens (such as, for example, zinc oxide), and surfactants are among the entities known to retard skin penetration of active agents. See, Angleini, G. Contact Dermatitis 7, 1981; Belmonte, J. Pharm Sci 67: 517, 1978; Catanzaro, J. M. J Am Acad Dermatol 24(1), 1981; Cooper, J. Pharm Sci 73: 1153, 1984; Faucher, J Am Oil Chem Soc 56: 776, 1979; Lahti, A. Contact Dermatitis 29, 1993; Trancik, R. J., Contact Dermatitis 8, 1982; Wahlberg, J. E. Acta Derm Venereol 64, 1984; Zatz, J. L. J Soc Cosmet Chem 34: 327, 1983.

ACCESSION NUMBER: 2001:78710 USPATFULL Full-text
 TITLE: Anhydrous topical skin preparations
 INVENTOR(S): Burnett, Katherine M., Basking Ridge, NJ, United States
 Kurtz, Ellen S., Ringoes, NJ, United States
 PATENT ASSIGNEE(S): Johnson & Johnson Consumer Companies, Inc., New Brunswick, NJ, United States (U.S. corporation)

	NUMBER	KIND	DATE
PATENT INFORMATION:	US 6239683	B1	20010529
APPLICATION INFO.:	US 1998-205474		19981204 (9)
DOCUMENT TYPE:	Utility		
FILE SEGMENT:	Granted		
PRIMARY EXAMINER:	Dudash, Diana		
ASSISTANT EXAMINER:	Berman, Alysia		
LEGAL REPRESENTATIVE:	Darby & Darby		
NUMBER OF CLAIMS:	26		

On this record, it is unclear why other materials included in Komer or Miller
 dreference would be different from the ones found in Cetaphil®. Applicants have not

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made it clear, in their specification or in their request for reconsideration, what they "regarded as constituting a material change in the basic and novel properties of the invention."

It is noted that the intended use recited in the claims are considered but the claims are properly included in this rejection because a recitation of the intended use(e.g. treatment of various condition such as acne) of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

MPEP 2100 also states that an old product into a kit will not render the claimed invention nonobvious even if the instructions detail a new use for the product). In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983).

All the critical elements required by the instant claims are obvious over Komer reference(US'422) in view of McDaniel and Miller.

Conclusion

1. No claim is allowed. Having carefully reviewed applicants' Request for Reconsideration, the examiner maintained the rejection in any respect.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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2. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579.

The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

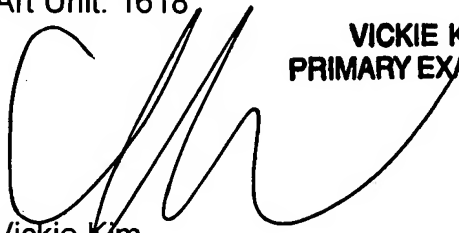
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**VICKIE KIM
PRIMARY EXAMINER**



Vickie Kim
Primary Patent Examiner
April 16, 2007
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